IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Nobivac DHP lyophilisate and solvent for suspension for injection for dogs

PRODUCT SUMMARY

EU Procedure number	IE/V/0161/001/MR
Name, strength and pharmaceutical form	Nobivac DHP lyophilisate and solvent for suspension for injection for dogs Live freeze-dried pellet for suspension for injection
Active substance(s)	Canine distemper virus Canine adenovirus 2 Canine parvovirus
Marketing Authorisation Holder	Intervet Ireland Ltd., Magna Drive, Magna Business Park, Citywest Road, Dublin 24.
Legal basis of application	Review application in accordance with Directive 90/677/EC
Date of Authorisation	12th November 2014
Target species	Dogs
Indication for use	For the active immunisation of dogs to reduce clinical signs of disease caused by canine distemper virus infection; to prevent clinical signs and viral excretion caused by canine parvovirus infection; to reduce clinical signs of canine contagious hepatitis and viral excretion due to canine adenovirus 1 infection and to reduce clinical signs of respiratory infection and viral excretion caused by adenovirus type 2 infection.
ATCvet code	QI07AD02
Concerned Member States	NO, UK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The initial application for the product was assessed before there was a requirement to produce a public assessment report due to implementation of Directive 2001/82/EC as amended by Directive 2004/82/EC in November 2005. Details on the quality, safety and efficacy of the product which led to the initial authorisation are not therefore included in the report.
Section VI of the report includes details of significant post-approval changes which have occurred since November 2005 which are considered important for the quality, safety and efficacy of the product.

II. QUALITY ASPECTS

See section I.

III. SAFETY ASSESSMENT

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the data submitted in the original application, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indication(s) as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet are updated on a continuous basis to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA's website.
This section contains information on significant changes made after approval which are important for the quality, safety or efficacy of the product.

Quality Changes

Summary of change	**Approval date**
Addition of the manufacturing site Novartis UK as an additional blending, filling and freeze-drying site for Nobivac DHP The data presented confirm Novartis UK to be a satisfactory alternative site for blending, filling and freeze-drying of Nobivac DHP. IE/V/161/001/II/005	29th January 2007
Update of a Certificate of Suitability for one of the gelatine sources used in the manufacture of Nobivac DHP. The information provided confirms that there is no change to the risk of transferring TSE agents associated with the update to the gelatine Certificate of Suitability. IE/V/161/001/IA/007	18th July 2007

Safety/Efficacy Changes

Summary of change	**Approval date**
Include Nobivac KC as a recommended vaccine for concurrent use with Nobivac DHP. A combined safety and efficacy study in which dogs were administered either Nobivac DHP alone, Nobivac KC alone or Nobivac DHP and Nobivac KC concurrently demonstrated that the range of adverse reactions observed following concurrent	01st July 2006

administration of the 2 vaccines was similar to that observed with the individual vaccines administered singly. The antibody titres measured for each of the active components of the Nobivac DHP vaccine and the level of protection observed following a combined canine parainfluenza virus and Bordetella bronchiseptica challenge infection were similar when the vaccines were administered concurrently or when Nobivac DHPor Nobivac KC was administered alone. On this basis, the concurrent administration of Nobivac DHP and Nobivac KC was not considered to adversely affect the safety or efficacy profile of either vaccine. IE/V/161/001/II/004	
Change the claim in relation to excretion of canine parvovirus (CPV) from 'to reduce viral excretion caused by CPV infection' to 'to prevent viral excretion caused by CPV infection'. Examination of CPV viral excretion data from a number of studies involving administration of a virulent CPV challenge to dogs vaccinated with the CPV component of Nobivac DHP and non-vaccinated dogs, indicated that all non-vaccinated dogs excreted CPV while CPV excretion was only observed in one vaccinated dog.As this incidence of CPV viral excretion among vaccinated dogs was recorded in an animal younger than 10 weeks old given a single CPV dose instead of the recommended 2 doses and therefore may be due to MDA interference, the proposed change in the claim in relation to CPV viral excretion to: 'to prevent viral excretion caused by CPV infection' is supported. IE/V/161/001/II/002	19th November 2006
Change the onset of immunity claim for the CAV2 component from 2 weeks after dosing to 1 week after dosing. Two challenge studies were performed involving administration of a single dose of the minimum titre of the CAV2 component included in Nobivac DHP to SPF puppies less than 10 weeks old. In one of the studies, the vaccinated pups as well as non-vaccinated control pups were challenge infected with a virulent CAV-1 challenge virus 1 week after vaccination while in the second study, the vaccinated pups as well as non-vaccinated control pups were challenge infected with a virulent CAV-2 challenge virus 1 week after vaccination. In each study, clinical signs and/or viral excretion associated with either CAV-1 or CAV-2 challenge infection in the vaccinated pups were reduced compared to non-vaccinated pups. On this basis, the 1 week onset of immunity claim in relation to protection provided by the CAV-2 component of Nobivac DHP is supported. IE/V/161/001/II/003	19th November 2006
Application for a compatible use claim for Nobivac DHP with the inactivated vaccines of the Nobivac series against canine leptospirosis. Change to SPC sections 4.6, 4.8, 4.9 and 6.2. Relevant studies have been performed which support the safety and efficacy of Nobivac DHP when reconstituted with the inactivated vaccines of the Nobivac series against canine leptospirosis caused by all or some of the following serovars: L. interrogans serogroup Canicola serovar Canicola, L. interrogans serogroup Icterohaemorrhagiae serovar Copenhageni, L. interrogans serogroup Australis serovar Bratislava, and L. kirschneri serogroup Grippotyphosa serovar Bananal/Liangguang.. SPC section 4.8 for Nobivac DHP has been amended to include details of this simultaneous administration schedule and to describe the associated adverse reactions. For consistency purposes, the adverse reactions currently described in the Nobivac DHP SPC Section 4.6 for the simultaneous administration of Nobivac DHP reconstituted with the Nobivac vaccine series against rabies are also moved to Section 4.8 of the SPC. IE/V/0161/001/II/012	18th June 2014